

## **REMARKS**

Claims 1-45 are currently pending in the application. Claim 34 is canceled. Claims 27, 30, and 43 are amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

### **Claim Objections**

The Examiner has objected to claim 30 as reciting “determining the presence of absence of a polypeptide”. Claim 30 has been amended to correct this typographical error.

The Examiner has objected to claim 34 for the lack of a period at the end of the claim. Claim 34 has been cancelled, and thus this objection is now moot.

### **Rejection of Claims 27-28, 30, 34, 35-43, and 45 Under 35 U.S.C. §112, First Paragraph**

The Examiner has rejected claims 27-28, 30, 34, 35-43, and 45 under 35 U.S.C. §112, First Paragraph for allegedly failing to comply with the written description and enablement requirement. The Examiner’s rejection is based largely on the assertion that the specification does not actually teach a polypeptide sequence which is encoded by the polynucleotide sequence of SEQ ID NO: 46, but instead teaches a predicted amino acid sequence which is likely to be encoded by the sequence of SEQ ID NO: 46 (i.e., SEQ ID NO: 47).

Without acquiescing to the Examiner’s rejection, Applicants have amended the claims to remove the reference to a polypeptide sequence “encoded by” the recited polynucleotide sequence. Thus, the claims now read on the direct detection of the polypeptide sequence of SEQ ID NO: 47, which is clearly described in the specification (see, e.g., SEQ ID NO: 47 in sequence listing). Applicants accordingly request that the rejection be reconsidered and withdrawn.

### **Rejection of Claims 27, 28, and 34 Under 35 U.S.C. §112, Second Paragraph**

The Examiner has rejected claims 27-28, and 34 under 35 U.S.C. §112, second paragraph as being indefinite. Claim 34 has been cancelled, and thus, the rejection is moot as to that claim. The Examiner has rejected claim 27 as indefinite in the recitation of “determining the phenotype of a cell...relative to a normal cell”. Although Applicants believe that the claim is clear and

unambiguous as written, and further, do not follow the Examiner's rationale for rejection, they have nonetheless amended claim 27 to recite a "colon cell" and a "normal colon cell". That is, the claim relates to a comparison between a "colon cell", which may or may not be normal, and a "normal colon cell" which is, obviously, normal. There is no vagueness as to this claim language. To the extent that the Examiner maintains the rejection on these grounds, Applicants respectfully request that the Examiner provide an explanation as to why one of ordinary skill in the art would find claim 27 vague with respect to the recitation of "colon cell" and "normal colon cell".

The Examiner has also rejected claim 27 as being indefinite in the recitation of "wherein the polypeptide is differentially expressed by at least a factor of two." The Examiner asserts that the claim lacks a step of correlating the differential expression to a particular phenotype, and inquires as to whether "expression in the "normal cell" is two times higher or lower than the unknown cell". At the outset, Applicants note that claim 27 does not recite an "unknown cell". The claims recite determining the phenotype of a "colon cell" by comparing the expression of a polypeptide comprising SEQ ID NO: 47 in the "colon cell" to the expression in a "normal colon cell." There is no "unknown cell", and thus it is unclear what the Examiner is referring to in this statement. To the extent that the Examiner maintains this rejection, Applicants respectfully request clarification of the Examiner's rationale for finding indefiniteness.

The specification teaches that the invention includes assays for determining the phenotype of a cell "e.g., whether the cell is (a) normal, or (b) cancerous or precancerous" (page 64, lines 1-2). Applicants have amended claim 27 to include the limitation that the phenotype is a "cancerous or precancerous phenotype" and have included a step correlating differential expression of the polypeptide to the phenotype of the recited cell. As to the Examiner's inquiry as to whether "expression in the "normal cell" is two times higher or lower than the unknown cell", Applicants submit that the term "differentially expressed" is clear from the claims and specification, and that no ambiguity exists. The specification teaches at page 16, lines 15-19 that differential expression includes upregulation and/or downregulation. The fact that "differentially expressed" can encompass an increase or decrease in expression does not render the term indefinite. Applicants submit that the claims are clear and unambiguous as written and respectfully request reconsideration and withdrawal of the rejections.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

Date:

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Name: ~~Matthew Beaudet~~

Registration No.: 50,649

Customer No.: 29932

Palmer & Dodge LLP

111 Huntington Avenue

Boston, MA 02199-7613

Tel. (617) 239-0100